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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,144	09/30/2003	Qingsheng Zhu	279.437US1	3925

21186 7590 10/17/2005

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
NATARAJAN, VIVEK	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	**Application No.** 10/677,144	**Applicant(s)** ZHU ET AL.	
	Examiner Vivek Natarajan	**Art Unit** 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-27* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it does not disclose the preferred embodiment of the invention, and because it uses phrases such as “an apparatus includes” which can be implied. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-6, 8-10, 14, 17-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (US Patent No. 6,212,416). Ward discloses an implantable glucose sensor having a disc-shaped sensor body 300 and a drug eluting polymeric matrix 302 with a time-controlled release profile, coated around the outer perimeter 304 of the sensor in order to minimize the formation of a fibrotic capsule around said sensor (see Fig.16A and the description thereof in col.11, line 15 – col.12, line 20).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3, 12-13, 15-16, 20 and 22-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claims 1, 9, 14 and 18 above, and further in view of Matsuda et al. (US Patent No. 5,462,976). Ward

discloses an implantable glucose sensor with multiple cavities 82a-d disposed on the sensor body (see Fig.5 and the description thereof in col.5, lines 40-53) and teaches that to minimize fibrotic tissue growth around the sensor, drugs such as dexamethasone and other corticosteroids can be incorporated into a polymer matrix disposed on the sensor that allows slow release of the drug locally. However, Ward does not specifically indicate that the drug eluting substance is precompressed with starch and disposed within the cavities of the device body. Matsuda teaches that drugs such as dexamethasone or platelet inhibitors may be incorporated into a glucosaminoglycan (GAG) hydrogel polymer matrix and compressed with starch into molded substances that may be disposed on the surfaces of medical devices to allow for controlled release of the drugs (col.18, line 17 – col.20, line 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to fill the cavities of the glucose sensor as disclosed by Ward with the drug eluting substance consisting of dexamethasone or a platelet inhibitor incorporated into a GAG polymer matrix and compressed with starch into a capsule as taught by Matsuda since this allows for controlled release of the drug locally.

5. Claims 7 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claims 1 and 18 above, and further in view of Allais et al. (US Patent No. 3,056,727). Ward discloses an implantable glucose sensor with a drug eluting substance disposed around the perimeter of the sensor, wherein the drug used is dexamethasone, but does not indicate that the drug is esterified prior to disposing the substance near the sensor. Allais teaches that hydroxylated steroids such as

dexamethasone may be esterified to prolong the duration of the steroid activity or to make the steroid more soluble (col.1, lines 15-46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug eluting substance as disclosed by Ward by esterifying the drug as taught by Allais since this allows the duration of the drug's activity to be prolonged.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 9 above. Ward discloses an implantable electrochemical sensor system for measuring blood analyte concentrations wherein a drug eluting substance is disposed on the sensor to prevent fibrotic growth around it, but only explicitly discloses a glucose sensor. However, the drug eluting layer as disclosed by Ward is not structurally or functionally limited to use with a glucose sensor. Official notice is taken that numerous blood monitoring sensors are well-known in the art that monitor one or more of bicarbonate, BUN, BNP, calcium, chloride, osmolarity, potassium, renin, or sodium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute in place of the glucose sensor as disclosed by Ward any of the aforementioned types of blood monitoring sensors that are well known in the art, since this allows for the detection of other analytes besides glucose. Such interchangeability of sensors which detect different types of analytes is well known to one having ordinary skill in the art.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 18 above, and further in view of Herweck et al. (Pub.No. US 2003/0153901 A1). Ward discloses an implantable electrochemical sensor system for

measuring blood glucose concentrations wherein a drug eluting polymeric coating is disposed as a tape around the perimeter of the sensor to prevent fibrotic growth around it. Ward does not disclose painting the drug directly on the device body. Herweck, however, teaches that an implantable device can be coated with a drug eluting polymer coating by painting the drug directly onto the surface of the cylindrical device (¶0007-0008). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of manufacturing a drug eluting implantable glucose sensor as disclosed by Ward by directly painting the drug on the sensor body as taught by Herweck since this allows the sensor to be coated with a drug eluting substance.

8. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to Claim 18 above, and further in view of Goldburt et al. (US Patent No. 4,900,136). Ward discloses an implantable glucose sensor with multiple cavities 82a-d disposed on the sensor body and teaches that to minimize fibrotic tissue growth around the sensor, drugs such as dexamethasone and other corticosteroids may be incorporated into a polydimethylsiloxane (PDMS) matrix, but does not indicate that the PDMS mixture is formed by mixing the drug with liquid silicone and then curing the mixture to form the solid PDMS. Goldburt teaches that PDMS may readily be synthesized by curing a mixture of liquid silicone components (col.4, lines 13-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to fill the cavities of the glucose sensor as disclosed by Ward with a mixture

of drug and liquid silicone and then cure the mixture as taught by Goldburt since this allows for the formation of a solid PDMS matrix within the cavity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN

ERIC F. WINAKUR
PRIMARY EXAMINER